AUG 15 2006

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K060423

Submitter:	Dako. 6392 Via Real Carpinteria, CA 93013 PH. 805.566.6655 FX. 805.566.0866 Establishment registration number: 2022180
Contact:	Tiffany D. Almeroth, RAC Manager, Regulatory Affairs PH. 805.566.3041
Date Summary Prepared:	May 12, 2006
Device Name(s):	CyAn™ DXD with Summit™ Software (Code CY204-30, CY205-30) MultiMix™ Triple-Colour Reagent (Code TC660) Anti-Human CD8/FITC Anti-Human CD4/RPE Anti-Human CD3/APC FluoroSpheres (Code K0110) Anti-human CD3 FITC (Code F0818) Anti-human CD3 RPE (Code R0810) Anti-human CD3 APC (Code C7225)
Device Classification:	Class II, Automated Differential Cell Counter 21 CFR 864.5220 Product code: GKZ
Panel:	Hematology and Pathology Devices Panel Division of Clinical Laboratory Devices.
Predicate Devices:	B-D FACS Calibur, K974360 Dako CD3/CD4 (FR875), K961701 Dako CD3/CD8 (FR881), K955909 Dako CD45/CD14 (FR700), K964974 BD CalBRITE Beads, K973483

Device Description:

The Dako CyAn™ DXD device is a bench-top flow cytometer system relying on

multiple (up to three) laser stimulation of fluorescence tagged lymphocytes. It is used with the Dako MultiMix, a triple color reagent; one each to CD3, CD4 and CD8, conjugated to fluorochromes APC(allophycocyanin), r-phycoerythrin, and fluorescein isothiocynate, which are balanced to identify the dual positive T-cell populations (CD3+CD4+ and CD3+CD8+) in peripheral blood lymphocytes. The instrument requires daily set-up with Dako FluoroSpheres consisting of a set of 5 bead populations having different fluorescent intensities and one non-fluorescent bead population. The combination of fluorochromes enables excitation by light of any wavelength from 365-650 nm. The CyAn DXD utilizes anti-human CD3 conjugated with FITC, RPE and APC to perform autocompensation.

Intended Use:

For *In Vitro* Diagnostic Use

CyAn™ DXD	The CyAn DxD Flow Cytometer with Summit™ software and user manual is intended for use as an In-Vitro Diagnostic device for identification and enumeration of the relative fraction of lymphocyte subsets in human peripheral whole blood using flow cytometry, i.e., identifies the relative percentages of CD4 and CD8 T-cells as demonstrated by gating on CD3 positive cells. TC-660, the three color combination, CD3, CD4 and CD8 is intended for use to identify the relative percentages of CD4 and CD8 positive T cells. Calibrators, Dako K0110 FluoroSpheres are intended for in vitro use on the Dako CyAn™ DXD flow cytometer with Summit™ software to adjust detector voltages and monitor daily instrument performance. CD3 FITC (Dako F0818), CD3 PE (R0810), and CD3 APC (C7225) single antibody-fluorochrome conjugates are intended to be used for setting fluorescence compensation parameters using automated compensation.

Substantial Equivalence:

The Dako CyAn™ DXD flow cytometer is substantially equivalent to the BD FACS Calibur whereby these instruments are used to identify and enumerate lymphocyte subsets using fluorescence gating and automated quality control algorithms. These products share similar technology and testing methodology. The additional parameters offered by the CyAn DXD for identification and enumeration over the predicate device does not introduce any new issues of safety and effectiveness.

Performance Characteristics:

Performance characteristics evaluated in support of the CyAn DXD and its associated components include results on linearity, precision, accuracy, specificity and carryover. Results of all testing conducted have demonstrated a substantial degree of equivalency to the predicate devices listed above.

Therefore, based on the information provided in this premarket notification, Dako

concludes that the devices listed above are safe, effective and substantially equivalent to their respective predicate devices in their indications for use, device design, materials, operational principles, and intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Tiffany D. Almeroth, RAC
Manager, Regulatory Affairs
Dako North America, Inc.
6392 Via Real
Carpinteria, California 93013

AUG 15 2006

Re: k060423
Trade/Device Name: CyAn™ DXD
Regulation Number: 21 CFR § 864.5220
Regulation Name: Automated differential cell counter
Regulatory Class: II
Product Code: GKZ
Dated: August 3, 2006
Received: August 8, 2006

Dear Ms. Almeroth:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Robert L. Becker, Jr., MD, Ph.D
Director
Division of Immunology and Hematology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K060423

Device Name: CyAn™ DXD

Indications For Use:

Clinical immunophenotyping using the CyAn DXD flow cytometer, a lyse wash sample preparation method, for identification and enumeration of CD3, CD4 and CD8 lymphocyte subsets using TC-660.

For In-Vitro Diagnostic Use

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

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